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RESMED

510(k) Summary – ResScan

[As required by 21 CFR 807.92 (c)]

K113815

Date Prepared	22nd February 2012
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Classification Reference	21 CFR 868.5895
Product Code	73 BZD
Common/Usual Name	Non continuous ventilator (IPPB)
Proprietary Name	ResScan
Predicate Device(s)	ResScan (K050775)
Reason for submission	New Device

Indication for Use

ResScan is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information, including the ability to remotely change settings.

It is intended to be used by Clinicians in conjunction with ResMed compatible flow generators, using ResMed's proprietary communications protocol.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate device.

- Similar intended use
- Same operating principle
- Same technologies
- Same manufacturing process

Design and Verification activities were performed on ResScan as a result of the risk analysis and design requirements. Verification testing included end-to-end testing to confirm that settings were successfully transferred between the flow generator and ResScan, and data captured by the flow generator was sent to ResScan. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device is substantially equivalent to the predicate device. The modified ResScan has not altered the safety and effectiveness when used for patient compliance management as an adjunct with ResMed flow generators. The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)

Non-Clinical Testing:

Performance testing of ResScan has been conducted using End-to-End bench testing methodology to demonstrate that the modified ResScan performs to design input specifications.

ResScan device met the predetermined pass/fail criteria as defined in the ResScan System Verification Report.

Clinical Testing:

Clinical testing was not deemed necessary as indentified in the Risk Analysis, as ResScan only obtains patient and machine information from therapeutic devices for which clinical trials have already been conducted, or compared with previous predicate comparison test results. Accordingly no clinical testing is required.

Device Description

The performance and functional characteristics of ResScan includes all the user friendly features of the predicate device.

ResScan allows the clinician to:

- Download and view patient and machine data from ResMed flow generators
- Store patient details
- Set machine parameters (Using Removal Media or PC direct connection)
- Create and print reports

- Uses Removal Media or PC direct connection as the interface between the flow generator and ResScan
- Support for Data Card Reader

Summary of additional features from the ResScan (K050775):

- ResMed compatible flow generators include, S8 series flow generators (73 BZD), VPAP Bilevel devices (73 MNS) and Stellar (73 MNT).
- Display/reporting of additional modes such as S, ST, ASV, iVAPS & PAC.
- Additional Windows Vista (64 bit) and Windows 7 (32 & 64 bit), and added support for remote settings via removable media – SD cards and USB sticks.
- Added support for display of alarm events.
- Added the capability to generate patient compliance reports based on US CMS guidelines – both on a per patient basis and across all patient data.

The inclusion of these features has been assessed within the risk analysis and no additional safety risks have been found as a result of the inclusion of the features.

Conclusion

The modified ResScan is substantially equivalent to the predicate device, ResScan (K050775).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ResMed, Limited
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Vice President, Clinical & Regulatory Affairs
ResMed Corporation
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San Diego, California 92123

MAR 2 7 2012

Re: K113815
Trade/Device Name: ResScan
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: BZD, MNS, MNT
Dated: February 23, 2012
Received: February 27, 2012

Dear Mr. D'Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

RESMED

Indication for Use

510(k) Number (if known):

Device Name: ResScan

Indication for Use

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113815

Prescription Use ___X___ AND/OR Over-The-Counter Use___

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)